

JUL 27 2000

K001739



XIII. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS COATED POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM

Manufacturer: Allegiance Healthcare Sdn. Bhd.
Plot 87 Kampung Jawa
Bayan Lepas
Penang, West Malaysia 11900

Regulatory Affairs Contact: Erica Sethi
1500 Waukegan Road, Bldg. WM
McGaw Park, IL 60085

Telephone: (847) 785-3337

Date Summary Prepared: May 24, 2000

Common Name: Patient Examination Glove

Classification: Glove, Examination (Latex)

Predicate Devices: Flexam Powder-Free Latex Examination Gloves With Protein Labeling Claim

Description: Coated Powder Free Examination Gloves With Protein Labeling Claim are formulated using latex and are coated with a Polyurethane coating. These gloves are offered non-sterile in sizes X-small, Small, Medium, Large and X-large.

Intended Use: Coated Powder-Free Latex Examination Gloves With Protein Labeling Claim are disposable devices intended for medical purposes that are worn on the examiner's hands or fingers to prevent contamination between patient and examiner. These gloves have been tested for use with chemotherapy drugs using ASTM F 739-99a.



XIII. STATEMENT OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (con't) COATED POWDER-FREE LATEX EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM

Substantial Equivalence Coated Powder Free Examination Gloves With Protein Labeling Claim are substantially equivalent to Flexam Powder-Free Latex Examination Gloves in that they provide the following characteristics:

- intended use
- size, design, product features
- made of natural rubber latex
- physical characteristics

Summary of Test Results:

<u>Test</u>	<u>Result</u>
Primary Skin Irritation	Glove does not display irritation potential.
Guinea Pig Maximization	Glove does not display sensitization potential.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber examination gloves per ASTM D3578-99.
Barrier Defects	Glove meets or exceeds requirements per 21 CFR §800.20 and ASTM D3578-99, AQL=2.5.
Powder Level	Glove meets powder level requirements for "Powder Free" designation per ASTM D 3578-99.
Protein Labeling Claim	Glove meets requirements for protein claim of 50 microgram or less of total water extractable protein per gram of glove using the ASTM Lowry test method (ASTM 5712-95).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 27 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Erica Sethi
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K001739
Trade Name: Polymer Coated Powder-Free Latex Examination
Gloves, contains 50 micrograms or less of total water
extractable protein per gram and Chemotherapy use claim
Regulatory Class: I
Product Code: LYY
Dated: May 25, 2000
Received: June 8, 2000

Dear Sethi:

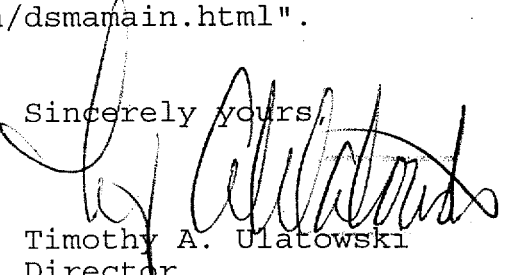
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



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Applicant: Allegiance Healthcare Corporation

510(k) Number: K001739

Device Name: Coated Powder-Free Latex Examination Gloves ~~With Protein Labeling Claim~~ and Chemotherapy Claim

Indications For Use: A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. This latex glove contains 50 micrograms or less of total water extractable protein per gram. In addition, this glove has been tested for use with chemotherapy drugs.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use X
(Per 21 CFR 801.109)

Chin S. Lin

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K001739